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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/637,221	08/08/2003	Randall M. Smith	400290	3334
27717	7590	66/21/2010	EXAMINER	
SEYFARTH SHAW LLP 131 S. DEARBORN ST., SUITE 2400 CHICAGO, IL 60603-5803			LAURITZEN, AMANDA L.	
ART UNIT	PAPER NUMBER			
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/637,221	<b>Applicant(s)</b> SMITH ET AL.
	<b>Examiner</b> Amanda L. Lauritzen	<b>Art Unit</b> 3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### **Status**

1) Responsive to communication(s) filed on 05 May 2010.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### **Disposition of Claims**

4) Claim(s) 1-53 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-53 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### **Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### **Priority under 35 U.S.C. § 119**

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### **Attachment(s)**

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_

5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

### **DETAILED ACTION**

This action is in response to communications filed 05 May 2010. Applicant pointed out that the objection to claims 1 and 46 should have been withdrawn with the previous amendment that resolved the issue. The associated objection is withdrawn.

Amendments to claims 1, 28, 41 and 46 recite “a predefined microwave waveform” to distinguish from the reference to Carr. However, the disclosure is not specific to the details of the waveform or that it is predefined or in which way(s) it is predefined. New grounds of rejection under the first paragraph of 35 U.S.C. 112 address this issue. Additionally, claim 41 has been amended to recite that reflected microwave energy from each breast independently is made use of. However, this feature is not described within applicant’s specification.

#### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant’s submission filed on 05 May 2010 has been entered.

#### ***Response to Arguments***

Applicant’s arguments have been fully considered but they are not persuasive and/or are moot in view of new grounds of rejection.

Applicant has contested that the reference to Carr is not configured to receive reflected microwave energy. The microwave detection apparatus of Carr, even though absent this specific term, does in fact receive reflected microwave energy, such that a microwave radiation can relay coded information (here a temperature signal). The waveguide 44 associated with the microwave probe 14, constitute antennas, as disclosed in the abstract. The probe assembly is shown at Fig. 2. The antennas are tuned to receive the microwave radiation, as also disclosed in the abstract.

The foam pads comprised of thermally insulating material (and therefore padded to some degree and contoured for comfort, as in col. 9, lines 25-42) shown in Fig. 6. The insulating pads dually function as a gridded orientation system that is pressed in contact with the breast, as shown in Fig. 6 and disclosed at col. 9, lines 43-60.

Claims 1, 28 and 41 have been amended to recite “a predefined microwave waveform” to distinguish from the reference to Carr. However, it is noted that the microwave energy administered by the system of Carr is in fact carried in an electromagnetic wave that is predefined such that it is coded with a quantity of radiation delivered, for example.

Applicant points to a deficiency in Carr – specifically, that the system is incapable of producing a 3-d image as pertinent to claim 5; it is conceded in the rejection that Carr is deficient in this regard, and the combination with Meaney et al. addresses this feature, as in section 4 of the office action. Meaney additionally discloses overlay of an optical image with the microwave graphical signal and specifically cites that the microwave renderings are “spatially co-registered” with a 3-D optical image, as claimed.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1-53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Amendments to claims 1, 28, 41 and 46 recite “a predefined microwave waveform,” but applicant’s disclosure is not specific to the details of the waveform or that it is predefined or in which way(s) it is predefined. Additionally, claims 41 has been amended to state that reflected energy is used from each breast independently; however, this feature is also absent from applicant’s specification and cannot be inferred from anything disclosed or depicted in the figures.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 2, 6, 7, 9, 10, 17-20, 21, 24-38, 41-46 and 49-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carr (US 5,983,124)

Carr discloses an apparatus and associated method for screening or diagnosing cancer in the breast of a patient, comprising: a support system for supporting the patient's breast in a fixed position; a microwave assembly including an antenna, source, receiver, and inherent processor; and an orientation system for orienting the surface of the breast in known positions with respect to the anatomy of the patient and locations of the antenna (microwave-transparent padded scan plate shown in Figs. 1 and 6 enables orientation of the breast in known positions relative to the position indicia and with respect to both the patient anatomy and antenna(s) located within the probe as in col. 4, lines 20-35; col. 5, lines 10-35; col. 9, lines 43-60; also col. 2, line 61 – col. 3, line 10, in which positioning is with respect to antenna(s)).

The method and system of Carr substantially includes all features of the claimed invention, but is not specific to providing a patient in a prone position on a table; however it would have been obvious to one ordinarily skilled in the art at the time of invention to modify the supine positioning of the patient, as disclosed in the system of Carr with a patient positioned in prone, such that the breast is positioned above the microwave-transparent padded scan plate of Fig. 1, rather than below, as it is known to skilled artisans to position patients in any of a number of positions for breast imaging scans, including both prone and supine positioning. Modifying the invention of Carr for prone patient positioning is a simple rearrangement of parts, as the method steps and technologies employed are applicable regardless of the orientation of the patient (and/or design of the patient supporting structure in how it accommodates or receives the patient). The system and method in the disclosure of Carr are identical to the claimed invention,

save for the basic modification required to image in a prone rather than a supine position, both of which have their advantages that are well-established in medical imaging of the breast tissue; for example, it is understood that the relative comfort of the patient is enhanced with apparatuses that accommodate positioning in the prone position.

The microwave detection apparatus of Carr receives reflected microwave energy, such that a microwave radiation can relay coded information (here, a temperature signal). The waveguide 44 associated with the microwave probe 14, constitute antennas, as disclosed in the abstract. The probe assembly is shown at Fig. 2. The antennas are tuned to receive the microwave radiation, as also disclosed in the abstract. The microwave energy administered by the system of Carr is in fact carried in an electromagnetic wave that is predefined such that it is coded with a quantity of radiation delivered, for example.

The foam pads comprised of thermally insulating material (and therefore padded to some degree and contoured for comfort, as in col. 9, lines 25-42) shown in Fig. 6. The insulating pads dually function as a gridded orientation system that is pressed in contact with the breast, as shown in Fig. 6 and disclosed at col. 9, lines 43-60.

Regarding claim 7, Carr discloses a microwave-transparent scan plate (shown in Figs. 1 and 6) but does not disclose the dielectric constant of the plate to be within the range of 1.7-9; however other materials of the apparatus are disclosed within that range (e.g., the probe at col. 8, lines 46-54). Because the plate is microwave-transparent and appropriate for imaging, it is understood that this component of the apparatus is also within this dielectric range.

Regarding claim 10, Examiner understands an air gap of less than 3 mm to be provided between the antenna and scan plate of the apparatus of Carr as the antenna is disclosed to make

intimate contact (col. 5, lines 32-35), which is most broadly interpreted to encompass close proximity and/or material touching.

Regarding claim 21, Carr does not expressly disclose digital camera viewing means, but it would have been obvious to provide a digital camera imaging system, as digital imaging system are well known in the art to provide convenience and flexibility for image acquisition, processing, and viewing.

Regarding claim 25, the support member is taken to be the grid/scan plate (of Figs. 1 and 6) of the Carr reference.

Regarding claims 32-33, archiving displayed image and patient data are take as image and data storage means as disclosed in Carr.

3. Claims 3-5, 8, 21, 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carr, as applied to claim 2 above, further in view of Meaney et al. (US 2004/0077943).

Carr discloses all limitations of the invention as substantially claimed including examination of the armpit area (auxillary gland at col. 2, line 65) and as detailed above, but does not disclose incorporating an optical camera in the microwave imaging system; however, in the same field of microwave array imaging, Meaney et al. teach acquiring optical images that are to be overlaid with the microwave scan images (par. 14, in which microwave images are “spatially co-registered” with a 3-D optical image; see also claim 70 for overlaying with a 3-D optical image). It would have been obvious to one of ordinary skill in the art at the time of invention to combine the optical imaging system with the microwave imaging system as taught by Meaney

for the purpose of corresponding microwave-detected internal abnormalities with a specific visual reference of the breast exterior (for motivation, see par. 54 of Meaney et al.).

Regarding claim 21, neither Carr nor Meaney expressly disclose digital camera viewing means, but it would have been obvious to provide a digital camera for the optical imaging means disclosed with the microwave/optical imaging system of Meaney as digital imaging systems are well known in the art to provide convenience and flexibility for image acquisition, processing, and viewing.

Regarding claim 22, the antenna contained within the probe of Carr is disclosed to move along coordinates (refer to Fig. 6 for coordinate grid; see also col. 9, lines 43-60), but this movement is not disclosed as provided by a motorized system; however, movement of the antenna disclosed by Meaney is provided with an actuator/drive shaft (paras. 12-13). Since movement of the antenna of Meaney does not require physical placement on the part of the medical examiner, the drive shaft inherently includes some sort of motorized system (additionally, a motor is a simple means of actuation that is well known in the art). It would have been obvious to include a motorized actuator as described by Meaney for movement of the antenna along coordinates as disclosed by Carr in order to enhance accuracy and precision by automating placement of the probe.

4. Claims 11, 12, 13-16, and 39-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carr '124 in view of Haddad et al. (US 6,454,711).

Carr discloses all features of the invention as substantially claimed but does not include microwave absorbing material, but in the same field of endeavor Haddad et al. disclose

microwave absorbing material (col. 3, line 27). It would have been obvious to incorporate use of a microwave absorbing material for the purpose of reducing residual crosstalk between the antennas of the apparatus of Carr (for motivation, see Haddad col. 3, lines 27-28).

5. Claim 23 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carr '124 in view of Horton et al. (US 5,168,514).

Carr discloses all features of the invention as substantially claimed but does not include an adjustable upper surface section of the examination table that enables the patient to sit in an upright position; however, Horton et al. disclose adjustable back-rests and other surfaces as part of an examination table that provide a patient with support in a seated position while undergoing medical procedures in which breast tissue is targeted (col. 2, lines 44-47). It would have been obvious to one of ordinary skill in the art to provide the breast examination table of Carr with adjustable support members disclosed by Horton in order to position the patient such that the targeted anatomy is fully accessible to the medical examiner.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda L. Lauritzen whose telephone number is (571)272-4303. The examiner can normally be reached on Monday - Friday, 8:30am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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